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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,786

01/11/2005

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Q85726

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23373 7590 03/03/2008
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EXAMINER

DEES, NIKKI H

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

03/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,786	Applicant(s) LEADBEATER ET AL.	
	Examiner Nikki H. Dees	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 March 2005, 28 September 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims starting with the second claim 54 been renumbered 56-70.

2. Claims 10, 27, 29, 68 and 70 objected to because of the following informalities: change all occurrences of "erithrithol" to "erythritol". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the claim language whether tablet base

Art Unit: 1794

material the first and second integral parts must be the same, or whether one may be sugar and the other polyol.

5. Claims 39 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 39 and 46 claim a tabletted chewing gum sweet having several layers. It is unclear how many layers "several" is meant to encompass.

6. Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 65 claims that the chewing gum tablet comprises a "dental vehicle." The examiner understands "dental vehicle" as a composition used to deliver desired components to the oral cavity including the teeth. The chewing gum tablet itself may act as a "dental vehicle," but will not contain a dental vehicle. The examiner will interpret the claim as a chewing gum table containing an agent with anti-dental caries activity.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 12, 14-34, 36-37, 39-41, 43-44, 53, 55, 57-59, 61-64, 67-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Beringer et al. (4,139,589).

9. Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol). The gum base is present at about 60 % in Example 2 (col. 8). The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8). Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be different colors (col. 4 lines 8-12). The tableted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient. These teachings anticipate Applicants' claims 1-4, 12, 14-15, 17-19, 25-34, 36-37, 39-41, 43-44, 53, 55, 57-59, 61-64 and 67-70.

Art Unit: 1794

10. Beringer et al. state that their product may have one layer that is hard and one layer that is plastic (col. 1 lines 31-34). This would result in an initial crunchy then chewy sensation, thus anticipating Applicants' claim 16.

11. Beringer et al. also teach a process for making their layered tablet. The chewing gum base may be mixed with the tablet base (Example 2, col. 8). The tablet mass is granular and pelletized. The granulate gum base is then pressed to the plastic (tablet base) portion of the tablet (col. 2 lines 3-11). Additional layers may be added as shown in Fig. 10. and col. 6 lines 30-45. These teachings anticipate Applicants' claims 20-22.

12. Beringer et al. also prepare their layered tablet with an indentation. The first layer is compressed with an indentation. The second part (gum base) is added to the material. An additional layer is fed into the press and compressed to cover the plastic mass (gum base) inserted in the center (Fig. 6 and col. 5 lines 7-17). These teachings anticipate Applicants' claims 23 and 24.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 5-7, 13, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589).

Art Unit: 1794

15. Beringer et al. teach a layered tablet chewing gum as applied to claims 1, 25, and 39 above.

16. Beringer et al. are silent as to the layers having a different thickness.

17. Regarding claims 5-7, 13, 35, and 42, it would have been obvious for one of ordinary skill in the art at the time the invention was made to have varied the thickness of the layers as taught by Beringer et al. in order to provide more (or less) of one of the components of the tablet. As the thickness of the layers may be varied, the weight ratio of the layers may also be varied. The tablet as taught by Beringer et al. could be easily modified by one of ordinary skill without undue experimentation. There would have been a reasonable expectation that the resulting tablet would maintain its favorable chewing gum properties.

18. Claims 8-10 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805).

19. Beringer et al. teach a layered tablet chewing gum as applied to claims 1 and 53 above.

20. Beringer et al. are silent as to the same sugar or polyol being used as the tablet base in both the first (gum base) and second (outer layer) of their invention. Beringer et al. are silent as to the use of a plasticized rubber or polymer for the gum base. They are also silent as to their invention containing a dental vehicle or breath freshener.

21. Cherukuri et al. teach a tabletted chewing gum composition that is made by compression (Abstract). Their invention is taught with both a nutritive sweetener (sugar)

Art Unit: 1794

and sugar-free using sorbitol (col. 11 Examples IV and V). Cherukuri et al. teach a number of compounds that may be use for the gum base including polymers (col. 6 lines 14-20). They also teach their invention comprising fluorides for tooth decay (col. 9 lines 34-35) and flavoring agents including spearmint oil and oil of wintergreen (col. 8 line 1).

22. Regarding claims 8 and 10, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polyol as taught by Cherukuri et al. along with gum base, as well as in the outer layers as taught by Beringer et al. Beringer et al. teach the use of sorbitol in the outer layer (Example 2) and Cherukuri et al. teach the use of sorbitol blended with the gum base for the production of a tabletted chewing gum. One of ordinary skill desiring to produce a sugar free product would be able to substitute sorbitol for the sugar in the invention of Beringer et al. This would not have required undue experimentation on the part of the artisan, and the resultant sugar-free product would have been expected to maintain its favorable taste and chewing properties.

23. Regarding claim 9, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a chewing gum base other than the chicle as taught by Beringer et al. One of ordinary skill would have been familiar with other gum bases as taught by Cherukuri et al. and would have been able to substitute a different gum base for the chicle without undue experimentation in order to impart the desired "chewiness" in their product. There would have been a reasonable expectation that the resultant product would have maintained its favorable chewing properties.

Art Unit: 1794

24. Regarding claims 65-66, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the flavoring agents and fluorides to prevent tooth decay as taught by Cherukuri et al. with the chewing gum composition as taught by Beringer et al. The composition of Beringer et al. is taught comprising other pharmaceutical agents, though not the specific ones as claimed. One of ordinary skill could have taken the additional components as taught by Cherukuri et al. and added them to the composition of Beringer et al. without undue experimentation. The resultant product would have been expected to have the desired dental vehicle or breath freshening properties while still maintaining its favorable chewing and taste properties.

25. Claims 11, 38, 45-52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Fisher et al. (4,370,350).

26. Beringer et al. teach a layered tablet chewing gum product as applied to claims 1, 25, 39 and 53 above.

27. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

28. Fisher et al. teach a tabletted chewing gum product made by compression (col. 1 lines 65-67). They go on to state that the particles being compressed passed through a 20 to 80 mesh screen (177 μm to 841 μm) and easily tableted on conventional machinery (col. 4 lines 56-58).

Art Unit: 1794

29. Regarding claims 11, 38, 45 and 54, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the particle size as taught by Fisher et al. for the production of the tabletted chewing gum product of Beringer et al. The products are being produced by the same technology, and Fisher et al. state that they have favorable results when tableting their product. Therefore, it would have been obvious to use the same particle size in the layered product of Beringer et al. There would not have been undue experimentation required to make this modification to the product of Beringer et al., and the resultant tablets would have been expected to maintain their chewing and flavor characteristics.

30. Regarding claims 46-52, the product of Beringer et al. is taught as having multiple layers of the same thickness as detailed above. The product also comprises about 60% of gum base (chicle) and the layers may be different colors, also as detailed above.

31. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

32. Fisher et al. teach a tabletted chewing gum product made by compression comprising particles ranging in size from 20 to 80 mesh (177 μm to 841 μm) as noted above.

33. Motivation for combining Beringer et al. and Fisher et al. in respect to claims 46-52 is the same as the motivation as applied above to claims 11, 38 and 54. One of ordinary skill in the art would have expected this combination to result in a favorable chewing gum tablet.

Art Unit: 1794

34. Regarding claim 49 and the varying of the thickness of the layer, motivation for the variations in these thicknesses are the same as applied to claims 5-6 above. The adjustment of the thickness of the layers would not have required undue experimentation, and would not have adversely affected the efficacy of the product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (first Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees
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